UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,151	01/17/2001	Gilbert R. Gonzales	UNSP/ 04	6299

26875 7590 11/18/2004

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	**PAPER NUMBER**
3732	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/765,151	GONZALES ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-23 and 25-29* is/are rejected.

7)☒ Claim(s) *10,11 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 15-20, 22 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (US 5,458,879).

Singh et al. disclose an oral composition (chewable tablet or liquid) containing a coloring agent (FD&C Red #40) or marker wherein the composition coats and adheres to the throat (pharyngeal) and mucous membranes (col. 1, lines 55-65, col. 5, lines 65-67, col. 6, lines 1-10 and lines 55-58 and col. 9, example III). Visible coloration of the mucous membranes is an inherent property of a coloring agent such as FD&C Red #40.

Regarding claim 20, the half-life of the ingested marker is "comparable" to the half-life of the composition in the human system since the coloration caused by a dye such as FD&C Red #40 is not permanent.

Claims 15-20 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Schlichte (US 6,303,102).

Regarding claims 15 and 19, Schlichte discloses a marker in combination with one or more treatment drugs or medicaments or "composition" applied orally wherein the marker is a pigment or a dye providing visual evidence for gauging both the application and time since application of the medicament by the marker color appearing in the mouth (col. 1, lines 7-11 and lines 50-54; col. 2, lines 21-30 and lines 52-56; and col. 3, lines 22-25). Schlichte also discloses

that the marker can be any color and can be visible under a variety of lighting conditions, for example, visible light, infra-red light, ultra-violet light, monochromatic light or the like (col. 3, lines 17-21).

Regarding claims 16-18, Schlichte discloses that the markers are encapsulated or incorporated ("interspersed") in the composition (col. 4, lines 49-61).

Regarding claim 20, Schlichte further discloses that the presence or absence of the visible marker at the point of introduction of the medicament serves as an indicator that the recipient is clear of any residual medicament or drug, necessitating that the half-lives of the medicament and the marker be related or "comparable" (col. 3, lines 26-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlichte (US 6,303,102).

Schlichte teaches a therapeutic compound with a marker that passes into tissue in the mouth by visibly coloring the tissue in the mouth ("oral/pharyngeal cavity") providing visual evidence for gauging both the application of and time since application of a medicament wherein the color can be visually observed under a variety of lighting conditions such as visible light, ultra-violet light etc. (col. 2, lines 19-30 and col. 3, lines 22-25).

Although Schlichte does not specifically disclose coloration of the mucous or buccal membranes, it is the Examiner's position that the claimed tissues are only specific tissues of the generic disclosure "in the mouth" by Schlichte (see MPEP 2144.08).

The method steps of claims 1-7 and 28 are rendered obvious by the above discussion.

Regarding claim 3, a placebo is well known in drug trials wherein the patient is told that the "placebo" is a drug and is treated like a drug. Accordingly it would have been obvious to one

of ordinary skill in the art at the time the invention was made to provide a marker combined with a placebo in a drug trial for introducing the "placebo" as an actual drug.

Regarding claim 6, although Schlichte discloses that the marker composition is visible under a variety of lighting conditions such as ultraviolet light, etc., Schlichte does not disclose specific wavelength ranges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized violet-blue to blue light having a wavelength in a range of about 430 nm to 490 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlichte (US 6,303,102), as applied to claim 1, in view of Pather et al. (US 6,200,604).

The use of dyes such as carmine red and FD&C dyes in oral compositions is well known. Pather et al. teach the use of carmine, beta-carotene and FD&C dyes in oral compositions (col. 5, lines 1-6).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to use carmine, beta-carotene, FD&C dyes as a visible marker in the method of the Schlichte since it was known in the art to use these types of dyes in orally ingested compositions.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. in view of Pather et al. (US 6,200,604).

Singh et al. do not disclose carmine red as a colorant.

The use of dyes such as carmine red and FD&C dyes in oral compositions is well known. Pather et al. teach the use of carmine, beta-carotene and FD&C dyes in orally ingested compositions (col. 5, lines 1-6).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected carmine as the colorant in the composition of Singh et al. due to its suitability for oral consumption as taught by Pather et al.

Claims 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. in view of Blasé et al.

Singh et al. do not disclose multiple markers.

Blasé et al. disclose multiple markers in a pharmaceutical composition to provide an appealing color (col. 6, lines 3-8 and col. 7, lines 32-34).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided multiple markers in Singh et al. pharmaceutical composition, as taught by Blasé et al., to impart an appealing color to the Singh et al. pharmaceutical composition.

Regarding claims 25-27, different contact coloration and whether the color is visible to the naked eye or under fluorescent light is dependent on the type of dye present in the composition.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlichte, as applied to claim 15, in view of Pather et al. (US 6,200,604).

Schlichte does not specifically disclose the type of dye or pigment used in the marker composition.

The use of dyes such as carmine red and FD&C dyes in oral compositions is well known. Pather et al. teach the use of carmine, beta-carotene and FD&C dyes in orally ingested compositions (col. 5, lines 1-6).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected carmine or FD&C dyes as the dye in the marker composition of Schlichte due to their suitability for oral consumption as taught by Pather et al.

Claims 12-14, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlichte in view of Kell (US 5,776,783).

Schlichte discloses a formulation or composition with multiple medications. Schlichte discloses that markers with unique coloring characteristics can be provided which remain in tissue for a predetermined period of time (several hours, days etc.) and then spontaneously

disappear depending on the drug remaining in the system (col. 4, lines 44-48). See discussion of for claim 1.

Schlichte does not disclose a marker associated with each medicament.

Kell teaches a medical formulation or oral composition which has multiple medications and separate markers associated with each medication in the formulation to monitor compliance with drug ingestion (col. 5, lines 20-34).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to provide multiple medications and unique markers associated with each medication in the composition of Schlichte wherein each marker has a unique coloring characteristic and residence time in the tissue, to monitor compliance with drug ingestion as taught by Kell.

Regarding claims 26 and 27, Schlichte discloses that a marker associated with a medicament can be any color and is visible under a variety of lighting conditions, namely, visible light, ultra-violet light etc. (col. 3, lines 16-21).

The method steps of claims 12-14 are rendered obvious by the above discussion.

Allowable Subject Matter

Claims 10, 11 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response submitted on August 4, 2004 have been considered but are not persuasive with respect to claims 15-20 and 22. Applicants' arguments are with respect to claims 1-9 and 12-14 are moot in view of the new grounds of rejection in this office action.

Regarding rejections of claims 15-20 and 22 under 35 U.S.C. 102(b) as being anticipated by Singh, Applicants' arguments "that any observable coloration caused by the colorants in the Singh composition would be short-lasting or fleeting to be observed," or that "the amount of

coloring agent between 0.005 to 0.03 weight percent of the total composition is insufficient to cause an observable coloration" are not persuasive. It is noted that the features upon which applicant relies (i.e., the duration of coloring and what constitutes a "sufficient amount to determine compliance") are not recited in the rejected claims. The Examiner directs Applicants' attention to the well-known fact that over the counter cough syrups have coloring agents that color oral tissues upon consumption.

Regarding the rejection of claim 21 under 35 USC 103(a) over Singh et al. in view of Pather et al. and claims 23 and 25-27 over Singh et al. in view of Blasé, Applicants' arguments that "the amount of coloring agent in the Singh composition is not sufficient to cause significant coloring that is visually observable after ingestion," or "the coloring agent is not present in a sufficient amount to cause an observable patient in order to determine compliance," the Examiner maintains that the Singh et al. composition has a sufficient amount of coloring agent to cause coloration of oral tissues, as discussed above. The Examiner used Pather et al. only to illustrate the equivalence of carmine, beta-carotene and FD&C dyes, as suitable dyes for oral consumption.

Upon further consideration, the Examiner is reinstating the rejections of claims 15-20 under 35 USC 102(e) as being anticipated by Schlichte (US 6,303,102).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR Anuradha Ramana
November 15, 2004

EDUARDO C. ROBERT
PRIMARY EXAMINER